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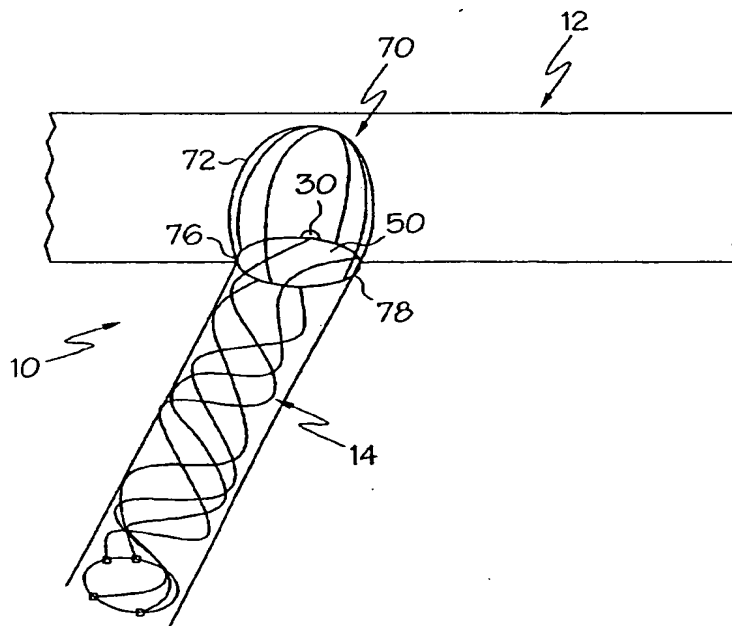
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(54) Title: BIFURCATED STENT



(57) Abstract: A bifurcated stent comprises a first stent section and a second stent section. Each stent section is expandable from a predeployed state to a deployed state independently from one another. The second stent section having an end engaged to a receiving region of the first stent section. In the deployed state the first stent section defines a primary flow path and the second stent section defines a secondary flow path in fluid communication with the first flow path. At least a portion of one or both the first stent section and second stent section is constructed from a wire member.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## TITLE

Bifurcated Stent

## CROSS-REFERENCE TO RELATED APPLICATIONS

- 5                   This application claims priority from U.S. provisional applications 60/271,506 filed February 26, 2001; U.S. provisional application 60/271,602 filed February 26, 2001; and U.S. provisional application 60/271,595 filed February 26, 2001; the entire content of each being incorporated herein by reference.

## 10   STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

## BACKGROUND OF THE INVENTION

- Stents, grafts, stent-grafts, vena cava filters and similar implantable medical  
15   devices, collectively referred to hereinafter as stents, are radially expandable endoprostheses which are typically intravascular implants capable of being implanted transluminally and enlarged radially after being introduced percutaneously. Stents may be implanted in a variety of body lumens or vessels such as within the vascular system, urinary tracts, bile ducts, etc. Stents may be used to reinforce body vessels and to prevent restenosis following  
20   angioplasty in the vascular system. They may be self-expanding or expanded by an internal radial force, such as when mounted on a balloon.

- Stents are generally tubular devices for insertion into body lumens. Balloon expandable stents require mounting over a balloon, positioning, and inflation of the balloon to expand the stent radially outward. Self-expanding stents expand into place when  
25   unconstrained, without requiring assistance from a balloon. A self-expanding stent is biased so as to expand upon release from the delivery catheter. Some stents may be characterized as hybrid stents which have some characteristics of both self-expandable and balloon expandable stents.

A vessel having a stenosis may be viewed as an inwardly protruding arcuate addition of hardened material to a cylindrical vessel wall, where the stenosed region presents a somewhat rigid body attached along, and to, the elastic wall. The stenosis presents resistance to any expansion of the vessel in the region bridged by the stenosis. Stenoses vary  
5 in composition, for example, in the degree of calcification, and therefore vary in properties as well.

A stent may be used to provide a prosthetic intraluminal wall e.g. in the case of a stenosis to provide an unobstructed conduit for blood in the area of the stenosis. An endoluminal prosthesis comprises a stent which carries a prosthetic graft layer of fabric and  
10 is used e.g. to treat an aneurysm by removing the pressure on a weakened part of an artery so as to reduce the risk of embolism, or of the natural artery wall bursting. Typically, a stent or endoluminal prosthesis is implanted in a blood vessel at the site of a stenosis or aneurysm by so-called "minimally invasive techniques" in which the stent is compressed radially inwards and is delivered by a catheter to the site where it is required through the patient's skin or by a  
15 "cut down" technique in which the blood vessel concerned is exposed by minor surgical means. When the stent is positioned at the correct location, the catheter is withdrawn and the stent is caused or allowed to re-expand to a predetermined diameter in the vessel.

U.S. Pat. No. 4,886,062 discloses a vascular stent which comprises a length of sinuous or "zig-zag" wire formed into a helix; the helix defines a generally cylindrical  
20 wall which, in use, constitutes a prosthetic intraluminal wall. The sinuous configuration of the wire permits radial expansion and compression of the stent; U.S. Pat. No. 4,886,062 discloses that the stent can be delivered percutaneously and expanded in situ using a balloon catheter.

U.S. Pat. No. 4,733,665 discloses an expandable intraluminal graft which is  
25 constituted by a tubular member formed from a plurality of intersecting elongate members which permit radial expansion and compression of the stent.

EP-A-0556850 discloses an intraluminal stent which is constituted by a sinuous wire formed into a helix; juxtaposed apices of the wire are secured to one another so that each hoop of the helix is supported by its neighboring hoops to increase the overall

strength of the stent and to minimize the risk of plaque herniation; in some embodiments the stent of EP-A-0556850 further comprises a tubular graft member to form an endoluminal prosthesis.

5 The devices cited above are generally satisfactory for the treatment of aneurysms, stenoses and other angeological diseases at sites in continuous unbifurcated portions of arteries or veins.

Within the vasculature however it is not uncommon for stenoses to form at a vessel bifurcation. A bifurcation is an area of the vasculature or other portion of the body where a first (or parent) vessel is bifurcated into two or more branch vessels. Where a stenotic lesion or lesions form at such a bifurcation, the lesion(s) can affect only one of the  
10 vessels (i.e., either of the branch vessels or the parent vessel) two of the vessels, or all three vessels. Many prior art stents however are not wholly satisfactory for use where the site of desired application of the stent is juxtaposed or extends across a bifurcation in an artery or vein such, for example, as the bifurcation in the mammalian aortic artery into the common  
15 iliac arteries.

For example, in the case of an abdominal aortic aneurysm ("AAA") in the infrarenal portion of the aorta which extends into one of the common iliac arteries, the use of one of the prior art prosthesis referred to above across the bifurcation into the one iliac artery will result in obstruction of the proximal end of the other common iliac artery; by-pass  
20 surgery is therefore required to connect the one iliac artery in juxtaposition with the distal end of the prosthesis to the other blocked iliac artery. It will be appreciated by a person skilled in the art that it is desirable to avoid surgery wherever possible; the requirement for by-pass surgery associated with the use of the prior art prosthesis in juxtaposition with a bifurcation in an artery therefore constitutes a significant disadvantage.

25 Another example of a vessel bifurcation is the left and right common carotid arteries. These arteries are the principal arteries of the head and neck. Both of the common carotid arteries are quite similar and divide at a carotid bifurcation or bulb into an external carotid artery and an internal carotid artery. In the region of the carotid bulb and the ostium of the internal carotid artery, stenoses present a particular problem for carotid stenting due to

the large tapering of the vessel interior from the common carotid artery (both the left and the right) to the internal carotid artery. The region of the carotid bifurcation or bulb happens to be where stenoses most often occur, particularly in the region of the ostium to the internal carotid artery in both of the carotid arteries.

5                   Embodiments of the present invention relate to endoluminal prosthesis (stents) that may be utilized in the region of a bifurcation of vessels. The present invention also embraces stent connecting means for connecting a stent (e.g. a stent which forms part of an endoluminal prosthesis or bifurcated stent) to another stent or portion thereof. Some  
10                   embodiments of the invention are directed to designs of bifurcated stents and their method of manufacture, as well as apparatuses and methods for introducing prostheses to the vasculature and methods of treating angeological diseases.

                  All US patents and applications and all other published documents mentioned anywhere in this application are incorporated herein by reference in their entirety.

                  Without limiting the scope of the invention a brief summary of some of the  
15                   claimed embodiments of the invention is set forth below. Additional details of the summarized embodiments of the invention and/or additional embodiments of the invention may be found in the Detailed Description of the Invention below.

                  A brief abstract of the technical disclosure in the specification is provided as well only for the purposes of complying with 37 C.F.R. 1.72. The abstract is not intended to  
20                   be used for interpreting the scope of the claims.

#### BRIEF SUMMARY OF THE INVENTION

                  The present invention includes many different embodiments. At least one embodiment of the invention is directed to bifurcated stents and the methods of treating  
25                   stenoses at a bifurcation site.

                  In some embodiments of the invention, the bifurcated stent includes at least one coiled member that defines at least one branch of the stent. In some embodiments the stent is characterized as having an expanding coil geometry. The expanding coil geometry provides at least one branch coil of the bifurcated stent with a larger diameter and/or a

tighter coil pitch. In some embodiments of the invention, the portion of the stent that is deployed into the main branch includes a coil pitch that is greater than the pitch of adjacent stent coils. The at least one coiled member may be characterized as wire, ribbon or a combination thereof. Preferably, the wire coil will have an elliptical or round cross-section, whereas a ribbon may be characterized as a flattened wire coil. The wire ribbon or coil may be constructed from an etched panel of stent material or be manufactured from laser cut tubing.

In some embodiments where the coil is constructed from at least one ribbon, the ribbon may define a loose pitch coil or a tight pitch coil. In embodiments where the ribbon defines a tight pitch coil, the ribbon is preferably constructed of Nitinol and/or Elgiloy. In embodiments where the ribbon defines a coil, the coil may have a substantially helical configuration.

In some embodiments of the invention a stent may be a generally tubular body having one more openings with at least one coiled member engaged thereto. The coiled member may define at least one branch of the bifurcated stent. The coiled portion and the generally tubular body may have similar or different physical and/or performance characteristics. For example, the generally tubular body may define a balloon expandable primary portion of the bifurcated stent, whereas the coiled portion may define a self-expandable branch of the bifurcated stent that extends from the primary portion subsequent to expansion of the primary portion.

In at least one embodiment, the coiled portion has a collapsed state and a delivered state. In the collapsed state the coiled portion is collapsed in upon itself within the plane of the tubular wall the primary portion. In the delivered state, the coiled portion extends outwardly from the primary portion to a predetermined length.

In at least one embodiment of the invention a bifurcated stent comprises a primary portion having at least one branch portion. The branch portion is a woven mesh defined by at least one wire. The primary portion defines at least one opening through which the branch portion may be passed and engaged thereto. The branch portion is delivered through the primary portion in a collapsed inverted state and is expanded to a delivered state

extending from the primary portion and in fluid communication therewith. Preferably, the woven mesh of the branch portion is constructed from Nitinol wire. In at least one embodiment, an end of the branch portion is welded to the area of the primary portion that defines the opening. Alternatively the wire of the branch portion is threaded through one or  
5 more flanges of the primary portion.

In at least one embodiment of the invention, the bifurcated stent includes one or more wire members which define a loop or loops within the interior of the primary section immediately adjacent to the opening through which a branch portion extends from. The loops preferably have a radius which is larger than the opening. The end of the branch  
10 portion immediately adjacent to the primary portion is engaged to one or more of the loops.

In at least one embodiment of the invention a bifurcated stent comprises a generally tubular primary portion which defines at least one side opening and two longitudinal openings. The bifurcated stent further comprises at least one coiled member which defines one or more side branches. Preferably, the at least one coiled member extends  
15 through the primary portion to provide a first coiled branch portion extending from the at least one side opening and a second coiled branch portion extending from at least one of the longitudinal openings. Preferably, the at least one coiled member is a wire and/or ribbon of Nitinol.

Additional details and/or embodiments of the invention are discussed below.  
20

#### BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

A detailed description of the invention is hereafter described with specific reference being made to the drawings.

FIG. 1 is a side perspective view of an embodiment of the invention in the  
25 deployed state.

FIG. 2 is a side perspective view of an embodiment of the invention.

FIG. 3 is a side perspective view of an embodiment of the invention in the deployed state.



FIG. 4 is a side view of an embodiment of the invention wherein the secondary branch is shown in the non-deployed state.

FIG. 5 is a side perspective view of the embodiment of the invention shown in FIG. 4 wherein the secondary branch is shown in the deployed state.

5           FIG. 6 is a side perspective view of an embodiment of the invention wherein a secondary branch of the bifurcated stent is shown in the collapsed inverted state prior to delivery.

FIG. 7 is a perspective view of the embodiment shown in FIG. 6 wherein the secondary branch is shown in the delivered state.

10           FIG. 8 is a close up view of a first optional interface between a primary branch and secondary branch such as may be used in the embodiments of FIGs. 6 and 7.

FIG. 9 is a close up view of a second optional interface between a primary branch and secondary branch such as may be used in the embodiments of FIGs. 6 and 7.

FIG. 10 is a side perspective view of an embodiment of the invention.

15           FIG. 11 is a close up view of the wire loop retaining members and secondary branch of the embodiment shown in FIG. 10.

FIG. 12 is a side perspective view of an embodiment of the invention wherein a coiled portion of a bifurcated stent extends outward from two openings of a primary stent section.

20           FIG. 13 is a side perspective view of an embodiment of the invention.

FIG. 14 is a side perspective view of an embodiment of the invention.

FIG. 15 is a cut-away perspective view of the embodiment shown in FIG. 14 shown deployed at a bifurcation site.

## 25   DETAILED DESCRIPTION OF THE INVENTION

As indicated above the present invention includes many different embodiments. In some embodiments the invention is directed to various designs of bifurcated stents. In FIG. 1 an example of a bifurcated stent is shown wherein the bifurcated stent, shown generally at 10, is comprised of at least two stent portions 12 and 14. Portions

12 and 14 are preferably self-expanding coils or coil members 16 and 18 of wire.

In the present application the term "wire" refers to a pliable strand of elongated material which provides structural support. A wire may be characterized as having an elliptical or cylindrical cross-section, or having a more ribbon-like, flattened cross-section. Where the wire has a substantially round or circular cross-section, in some embodiments the wire has a diameter of about .002 to about .008 mm. Where a particular characteristic of the wire used to form coil 18 is noteworthy the relevant characteristics is noted and/or discussed in greater detail.

Where the stent portions 12 and 14 are self-expanding coils 16 and 18, the coils may be constructed from a shape memory metal such as nitinol or elgiloy or a shape memory polymer.

In the embodiment shown the stent 10 is delivered to a bifurcation 20 by a catheter or other delivery device (not shown). Once the stent is in position either portion 12 or 14 may be initially deployed. For example, when in the stent 10 is in position at the bifurcation 20, in one embodiment, the second stent portion 14 may be deployed into the daughter branch 22 of the bifurcation 20. Following deployment of the second stent portion 14, the first stent portion may be delivered into the primary branch 24 of the bifurcation and the delivery system withdrawn.

Second coil 18 has a first end 30 and a second end 32. In the embodiment shown in FIG. 1, the first end 30 is welded to a receiving region 34 of the first coil 16. It must be noted however, that welding the coils 16 and 18 together is merely one option for securing the stent portions 12 and 14 together. The present invention is also directed to embodiments where the coils 16 and 18 are integrally formed with a connection point therebetween, or where the coils 16 and 18 are joined in any other manner suitable for connecting stent portions 12 and 14 together.

When both coils 16 and 18 are deployed, such as is shown in FIG. 1, the first coil 16 defines a primary flow path 48 and the second coil defines a secondary flow path 52. The flow paths 48 and 52 are in fluid communication with each other.

In addition to the above, it should also be noted that the location of the receiving region 34 on the first coil 12 may be anywhere along the length of the first coil 12.

As a result, end 30 of the second coil 14 may be engaged anywhere on the first coil 12.

Such variable engagement position allows the bifurcated stent 10 to be produced for use in a wide range of bifurcation areas.

Not only may the relative position of the engagement between the first stent portion 12 and second stent portion 14 be made variable, so to may the relative lengths of the portions be varied. For example, the first portion 12 may have a length 36 different from or the same as the length 38 of the second portion 14. The range of values appropriate to lengths 36 and 38 are limited by the particular application and anatomical constraints.

In order to provide stent support to the carina 26 the stent portions 12 and 14 may be provided with tighter or looser coil pitch as well as other different characteristics, such as diameter. For example, in one embodiment shown in FIG. 2, the first coil 16 has a diameter of approximately 4.0 mm, whereas the second coil 18 predominately has a diameter of approximately 3.0 mm. In addition, at least a portion 40 of the second coil 18 is provided with a larger diameter, relative to the rest of the coil 18. In the example shown in FIG. 2 the portion 40 has a diameter greater than about 3.0 mm. The larger diameter portion 40 of the coil 18 will extend toward the carina to provide for improved support and/or coverage of the region.

As indicated above, the portions 12 and 14 of the bifurcated stent 10 may have different physical properties, performance characteristics and be constructed from different materials from one another. In the embodiment shown in FIG. 3 for example, first stent portion 12 has a non-coiled configuration whereas the second stent portion 14 comprises a coil 18 such as described above. The non-coiled first portion 12, may be characterized as a tubular stent body 42 having a cellular design such as may be seen for example in the stents described in U.S. 6,348,065 and U.S. 6,013,091 the entire contents of each being incorporated herein by reference. Stent configurations other than those described in terms of a cellular configuration, such as for example the stents described in U.S. 6,033,433, the entire content of which is incorporated herein by reference, may also be used

as the non-coiled portion of the bifurcated stent 10. In an alternative embodiment of the invention, the first portion 12 may be characterized as a substantially solid or porous tubular member.

In the embodiment shown in FIG. 3 the body 42 of the first portion 12 defines  
5 a distal opening 44, a proximal opening 46 and a primary flow path 48 therebetween. The body 42 defines at least one secondary opening 50 which allows a secondary flow path 52 defined by the second portion 14 to be in fluid communication with the primary flow path 48.

The end 30 of the coil 18 may be engaged to any portion of the first portion  
10 adjacent to the secondary opening 50 by any manner desired. In at least one embodiment, end 30 of the second portion 14 is welded to a receiving region 34 of the first portion 12. The receiving region 34 may be located anywhere on the body 42 of the first portion 12.

The first portion 12 and the second portion 14 may function as, and may in  
fact be, distinct stent structures that are simply engaged together at the receiving region 34 to  
15 form the bifurcated stent 10. Either or both portions 12 and 14 may be balloon expandable, self-expandable or may have hybrid stent features.

In some embodiments, where the second stent portion 14 defines a coil 18,  
such as shown in FIG. 3 above, a self-expandable coil 18 may tightly packaged into a pre-  
deployment collapsed configuration, such that prior to deployment the coil 18 is contained  
20 substantially within deployed first portion 12 and/or contained in the collapsed state adjacent thereto, such as is shown in FIG. 4. The tightness of the coil packaging and the characteristics of the delivery catheter 90 will determine the extent to which the coil 18 is contained internally or externally relative to the first portion 12. Preferably, prior to delivery of the second portion 14, the second portion 14 will not extend beyond the outer diameter 92  
25 of the first portion 12.

As is shown in FIG. 5, following delivery of the first portion 12, the second  
portion 14 is allowed to self-expand into the secondary branch (shown in FIG. 4) as directed  
by the guide wire 66.

In an alternative embodiment of the invention shown in FIGs. 6 and 7, the second portion 14 is a woven body 60 comprised of one or more fibers 62 rather than a single coil 18 as previously described. The individual fiber(s) 62 of the woven body 60 may be a wire or ribbon of appropriate stent material, such as nitinol. The woven body has a first end 30 and a second end 32. At first end 30 one or more fibers 62 are secured to the first portion 12 at one or more receiving regions 34 distributed about the secondary opening 50.

As is shown in the close-up partial view of the secondary opening 50 shown in FIG. 7, the fibers 62 may be welded to the receiving regions 34. Alternatively, in the embodiment shown in FIG. 8, the fibers 62 may have one or more loops or flanges 64 which are looped through or otherwise engaged to the receiving regions 34.

The woven body 60 of the second portion 14 has a unique configuration which allows it to be deployed from a collapsed state within the previously deployed first portion 12 shown in FIG. 6 to a fully deployed state shown in FIG. 7 where the second portion 14 is external and adjacent to the first portion 12.

As is shown in FIG. 6, prior to deployment, the collapsed body 60 is within the primary flow path 48 of the first portion 12. In some embodiments, the woven body 60 may extend out one of the proximal or distal openings 44 or 46 as shown. When the woven body 60 is deployed, the body 60 will self-expand inverting its shape as it passes through the secondary opening 50 and into the secondary branch 22. When the body 60 has fully inverted its configuration relative to the secondary opening 50 and fully expanded into the secondary opening 22, the second portion 14 of the stent 10 is fully deployed as shown in FIG. 7. In some embodiments it may be useful to retain a guide wire 66 at the bifurcation 20 in order to guide the inversion and expansion of the second portion 14 through the opening 50 and into the secondary branch 22.

In yet another embodiment of the invention shown in FIG. 10, the bifurcated stent 10 may be provided with a unique engagement mechanism between the first portion 12 and second portion 14 to provide for a wide range of articulation between the respective portions. In the embodiment shown in FIG. 10, the first portion 12 and second portion 14 may be have similar or different stent characteristics independent of each other. In at least

one embodiment, the first portion 12 acts as a balloon expandable stent and the second portion 14 acts as a self-expandable stent. Preferably, the second portion 14 has a spiral or helical configuration similar to that of stents described in U.S. 6,042,597, the entire content of which is incorporated herein by reference.

5               The second portion 14 is engaged to the first portion 12 through a unique wire assembly 70 which acts to moveably engage the end 30 of the second portion 14 to the secondary opening 50 of the first portion 12.

Wire assembly 70 is comprised of one or more wire or ribbon members 72 which are disposed within or about the first portion 12 adjacent to the secondary opening 50.

10       In some embodiments a plurality of members 72 converge and are engaged to the first portion at one or more primary engagement points 74. The ends 76 of each member 72 extend toward the secondary opening 50 where they are each engaged to a secondary engagement surface 78 located at or around end 30 of the second portion 14. In some  
15       embodiments the ends 76 may also be engaged to portions of the first portion 12 adjacent to the secondary opening 50 at secondary engagement surfaces 78.

              In the embodiment shown in FIG. 11, the members 72 are constructed and arranged to provide a wire assembly 70 that has a diameter larger than that of the secondary opening 50. Wire assembly 70 is engaged to the end 30 of the second portion 14 as  
20       described above. However, the wire assembly is only frictionally engaged to the first portion 12 where the members 72 contact the area of the first portion 12 that defines the secondary opening 50. This type of engagement provides the secondary portion 14 with a rotatable ball-joint type connection to the first portion 12 thereby providing the second portion with a relatively large degree of articulation relative to the first portion 12.

              In the various embodiments of the invention discussed thus far, a bifurcated  
25       stent 10 may include a first portion 12 and a second portion 14 such as has been previously described. However, in the embodiment shown in FIG. 12 it is shown that the invention is also directed to a bifurcated stent 10 having a third portion 15 as well.

              In the embodiment shown in FIG. 12, the first portion 12 is preferably a non-coiled stent such as previously described in relation to FIG. 3. The first portion 12 may be

any type of stent design, however in at least one embodiment the first portion 12 acts as a balloon-expandable stent. In contrast to the first portion 12, the second and third portions 14 and 15 are characterized as a single self-expanding coil 18 that defines each portion 14 and 15. Coil 18 is preferably constructed of nitinol wire. A portion 80 of the coil 18 connects the second portion 14 to the third portion 15 by extending from the end 30 of the second portion 14 to the end 82 of the third portion 15. The portion 80 of the coil that connects the two portions 14 and 15 together passes from the secondary opening 50 to one of the proximal or distal openings 44 or 46 through the primary flow passage 48 of the first portion 12.

In the deployed state shown in FIG. 12, the second portion 14 extends radially away from the first portion 12 to provide a secondary flow path 52 that is in fluid communication with the primary flow path 48 via opening 50. In the deployed state the third portion 15, extends longitudinally from opening 44, or optionally opening 46, thereby extending the primary flow path 48 and stent support further into vessel 24.

Portion 80 frictionally engages the interior 84 of the first portion 12 thereby coupling the second and third portions 14 and 15 to the first portion 12 without welds or other relatively rigid engagement mechanisms.

As indicated above the various bifurcated stent designs discussed thus far may include second portions 14 and/or first portions 12 that are constructed from a coil 18 of nitinol or other shape-memory wire or ribbon. In the embodiments shown in FIGs. 13-15 the bifurcated stent 10 is clearly shown having a coil 18 constructed from a ribbon 19. In the embodiments shown in FIGs. 13-15 the first portion 12 is preferably a substantially tubular stent body having a non-coiled configuration such as described above in the description of FIG. 3. In the various embodiments shown in FIGs. 13-15 the diameter and pitch of the coil 18 may be varied. Similarly, the engagement between the first portion 12 and the second portion 14 may likewise be provided for by any of the methods or mechanisms described above or that are otherwise known. In some embodiments, the first portion 12 and second portion 14 may be integrally formed with ribbon 19 may be an extension of the first portion 12.

In addition to being directed to the specific combinations of features claimed below, the invention is also directed to embodiments having other combinations of the dependent features claimed below and other combinations of the features described above.

5 The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

10 Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as  
15 alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each  
20 be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below.



## CLAIMS

1. A bifurcated stent comprising:
  - a first stent section, the first stent section being expandable from a predeployed state to a deployed state, in the deployed state the first stent section defining a  
5 primary flow path; and
  - a second stent section, the second stent section being expandable from a predeployed state to a deployed state, the second stent section having an end engaged to a receiving region of the first stent section, in the deployed state the second stent section defining a secondary flow path, the secondary flow path in fluid communication with the  
10 primary flow path, the first stent section the second stent section being expandable independently from one another, at least a portion of at least one of the first stent section and the second stent section being constructed from a wire member.
2. The bifurcated stent of claim 1 wherein the second stent section is constructed from  
15 at least one member of the group consisting of a coil of wire having a substantially circular cross-section, a flattened ribbon, an etched panel, laser cut tubing and any combination thereof.
3. The bifurcated stent of claim 2 wherein the first stent section is constructed from at  
20 least one member of the group consisting of a coil of wire having a substantially circular cross-section, a flattened ribbon, an etched panel, laser cut tubing and any combination thereof.
4. The bifurcated stent of claim 3 wherein the second stent section is constructed from  
25 the coil of wire, the coil of wire defining a first diameter and a second diameter.
5. The bifurcated stent of claim 2 wherein the first stent section comprises a substantially tubular body defining openings at both ends, the substantially tubular body

further defining a secondary opening, the receiving region being adjacent to the secondary opening.

6. The bifurcated stent of claim 5 wherein in the deployed state the first portion defines  
5 an outer diameter, when the first portion is in the deployed state and the second portion is in the predeployed state, the second portion has a length that does not extend substantially beyond the outer diameter of the first portion.

7. The bifurcated stent of claim 5 wherein in the deployed state the first portion defines  
10 an outer diameter, when the first portion is in the deployed state and the second portion is in the predeployed state, the second portion is substantially contained within the primary flow path defined by the first portion.

8. The bifurcated stent of claim 1 wherein the first stent section is balloon expandable  
15 and the second stent section is self-expandable.

9. The bifurcated stent of claim 1 wherein at least one of the first stent section and the second stent section are self-expandable.

20 10. The bifurcated stent of claim 1 wherein at least one of the first stent section and the second stent section are balloon-expandable.

11. The bifurcated stent of claim 1 wherein the wire is characterized as a flattened ribbon.  
25

12. The bifurcated stent of claim 1 wherein the second stent section comprises a wire mesh.

13. The bifurcated stent of claim 12 wherein the first stent section comprises a substantially tubular body defining openings at both ends, the substantially tubular body further defining a secondary opening, the receiving region being adjacent to the secondary opening.

5

14. The bifurcated stent of claim 13 wherein in the predeployed state the second stent section extends from the receiving region into the primary flow path defined by the first stent section.

10 15. The bifurcated stent of claim 14 wherein in the deployed state the second stent section extends from the receiving region and radially outward from the first stent section, the second stent section constructed and arranged being constructed and arranged such that when the second stent section is expanded from the predeployed state to the deployed state the position of the second stent section is inverted relative to the secondary opening.

15

16. The bifurcated stent of claim 12 wherein the wire mesh comprises a plurality of woven wires.

17. The bifurcated stent of claim 16 wherein receiving region comprises a plurality of the engagement points, the woven wires having ends, at least some of the ends being engaged to the engagement points.

20

18. The bifurcated stent of claim 17 wherein the at least some of the ends are welded to the engagement points.

25

19. The bifurcated stent of claim 17 wherein the at least some of the ends comprise a looped flange, each looped flange being moveably engaged to one of the engagement points.

20. A bifurcated stent comprising:

a substantially tubular stent body being expandable from a predeployed state to a deployed state, the substantially tubular stent body having openings at both ends and in the deployed state defining a primary flow path therethrough, the substantially tubular body  
5 further defining a secondary opening, the secondary opening having an opening diameter;

a secondary stent body, the secondary stent body being expandable from a predeployed state to a deployed state independently of the substantially tubular stent body, the secondary stent body having openings at both ends and in the deployed state defining a secondary flow path therethrough, one end of the secondary stent body being immediately  
10 adjacent to the secondary opening of the substantially tubular stent body; and

a wire engagement apparatus, the wire engagement apparatus comprising at least one wire member, at least a first portion of the at least one wire member being engaged to the substantially tubular member, at least a second portion of the at least one wire member being engaged to the end of the secondary stent body being immediately adjacent to the  
15 secondary opening of the substantially tubular stent body, the secondary stent body being moveable relative to the substantially tubular stent body.

21. The bifurcated stent of claim 20 wherein the secondary stent body is constructed at least partially from wire.  
20

22. The bifurcated stent of claim 21 wherein the secondary stent body is constructed at least partially from a shape memory material.

23. The bifurcated stent of claim 21 wherein the secondary stent body is self-expandable.  
25

24. The bifurcated stent of claim 20 wherein the wire engagement apparatus is substantially contained within the primary flow path of the substantially tubular body adjacent to the secondary opening.

25. The bifurcated stent of claim 24 wherein the at least one wire member is shaped to define an apparatus diameter, the apparatus diameter being larger than the opening diameter.

26. The bifurcated stent of claim 20 wherein the wire engagement apparatus is disposed  
5 about a portion of the substantially tubular body.

20. A bifurcated stent comprising:

a substantially tubular stent body being expandable from a predeployed state  
to a deployed state, the substantially tubular stent body having a proximal end and a distal  
10 end, the substantially tubular stent body defining a flow path opening at each end and in the  
deployed state defining a primary flow path therethrough, the substantially tubular body  
further defining a secondary opening; and

a secondary stent body, the secondary stent body comprising a wire member, the  
wire member defining a first coiled portion, a second coiled portion and connection portion  
15 therebetween, the secondary stent body being expandable from a predeployed state to a deployed  
state independently of the substantially tubular stent body, in the deployed state the first coiled  
portion being positioned immediately adjacent to the secondary opening of the substantially  
tubular stent body and extending radially therefrom, in the deployed state the second coiled  
portion being positioned immediately adjacent to one of the flow path openings of the  
20 substantially tubular stent body and extending longitudinally therefrom, the connection portion  
being frictionally engaged to the substantially tubular stent body.

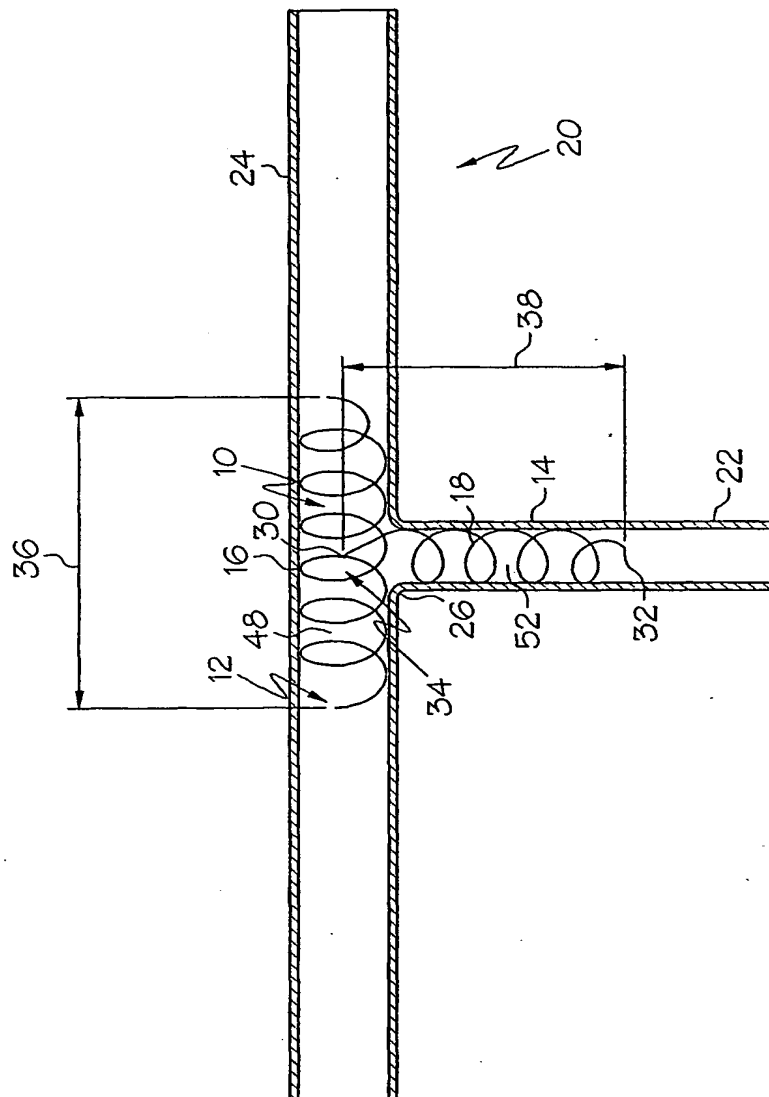


FIG. 1

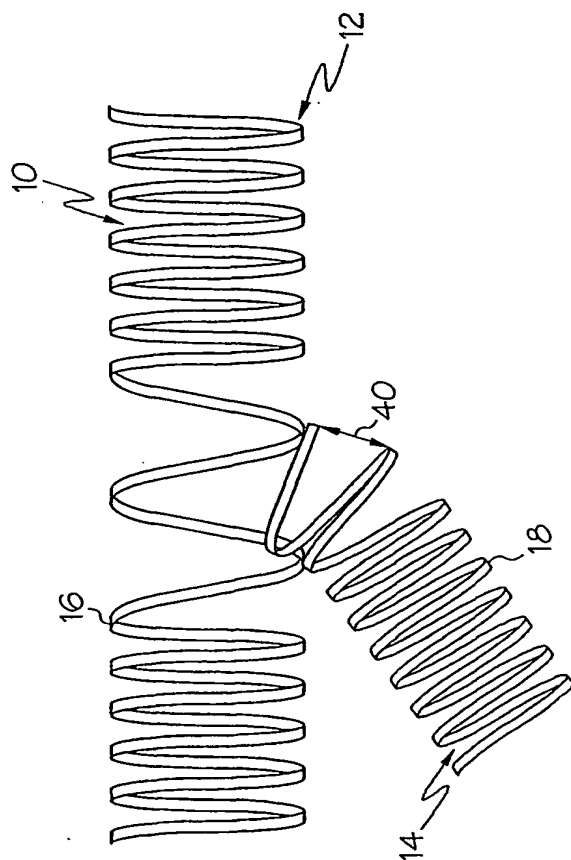


FIG. 2

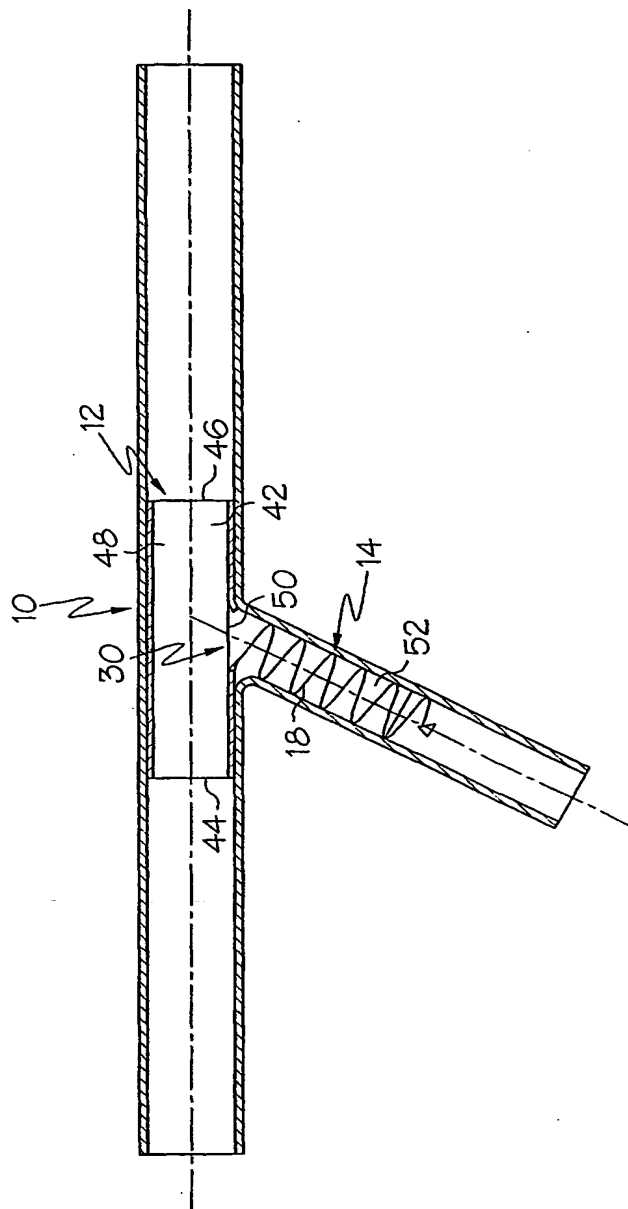


FIG. 3



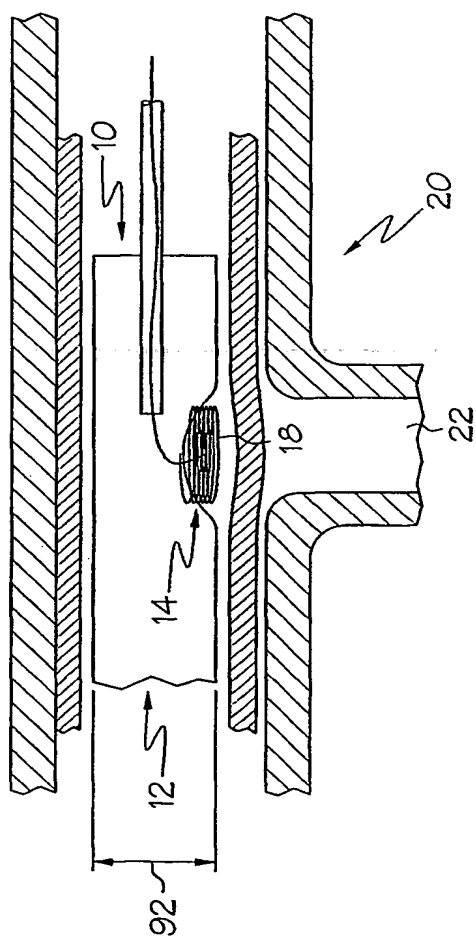
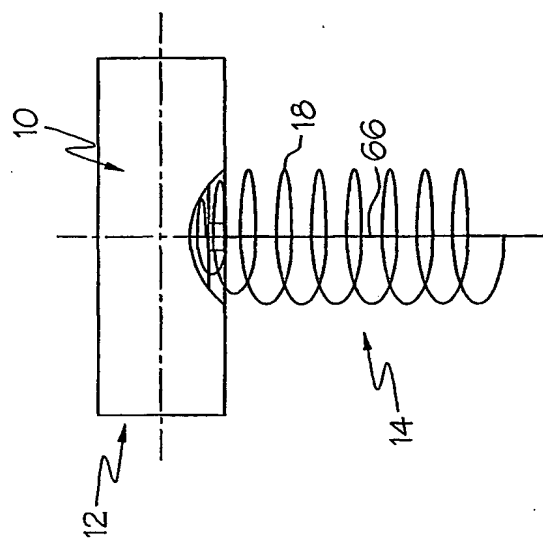
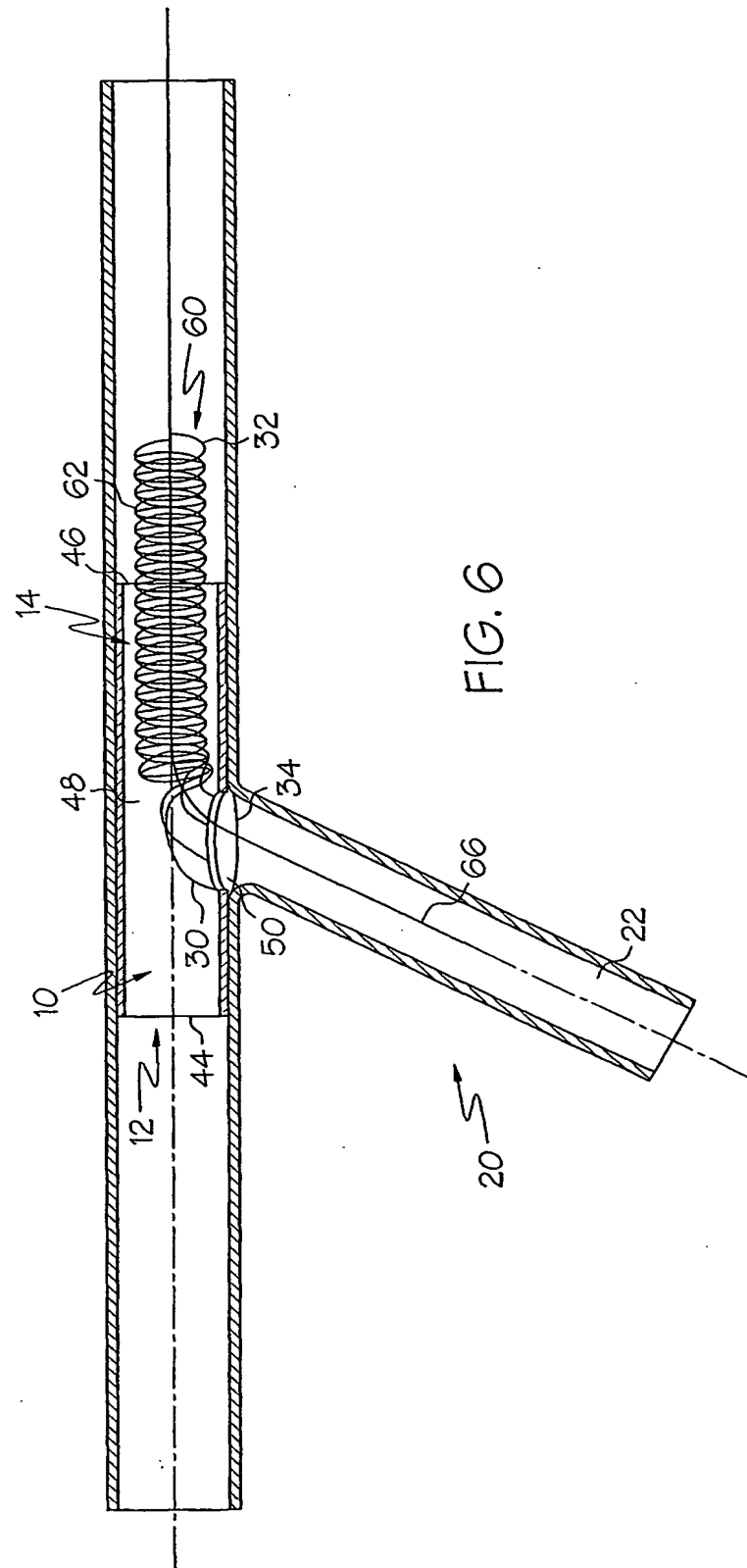
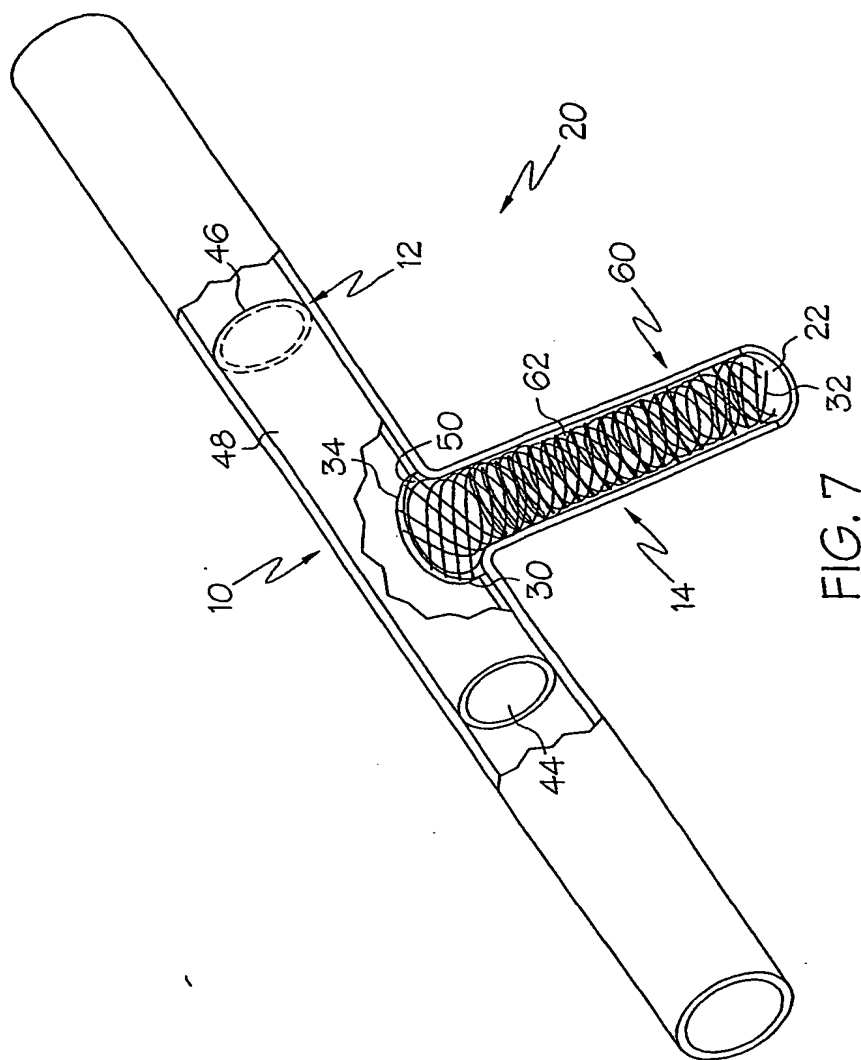


FIG. 4



50. G. F.





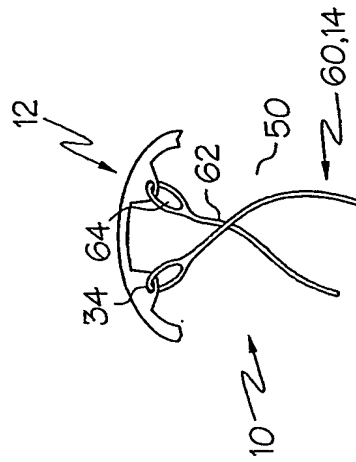


FIG. 9

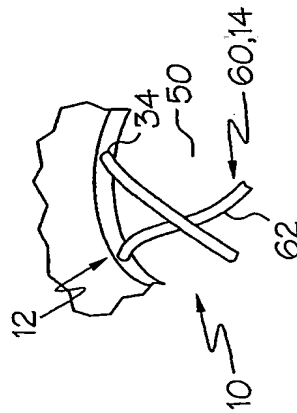


FIG. 8

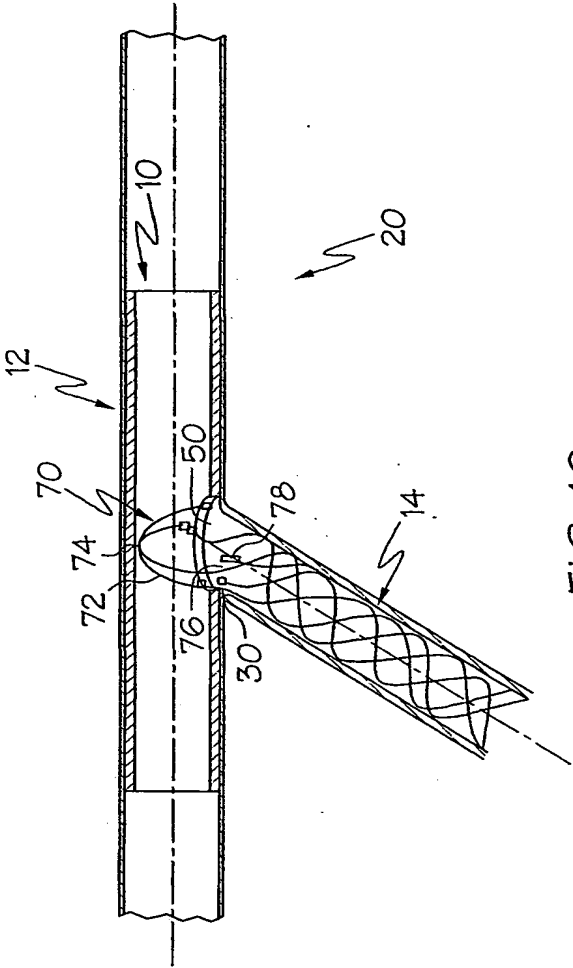
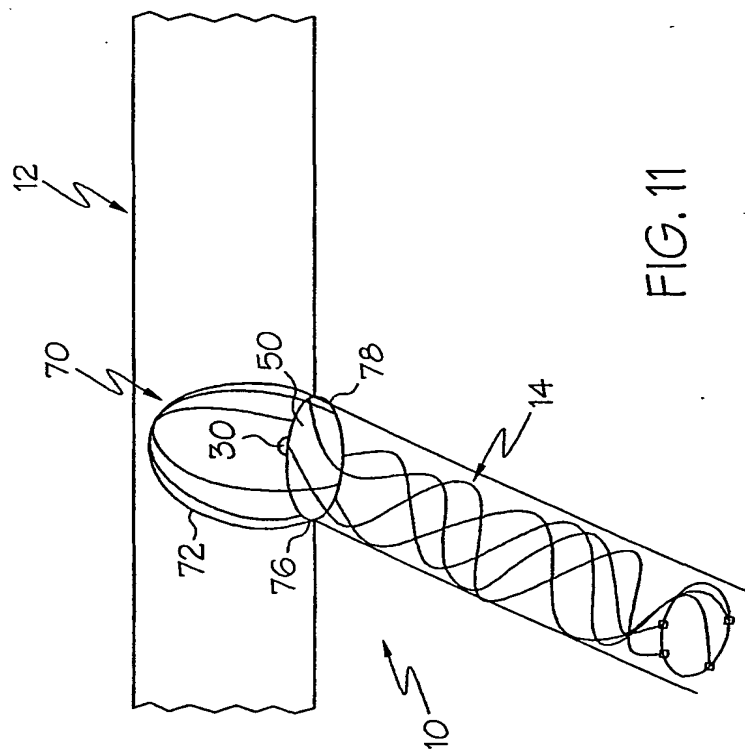


FIG. 10



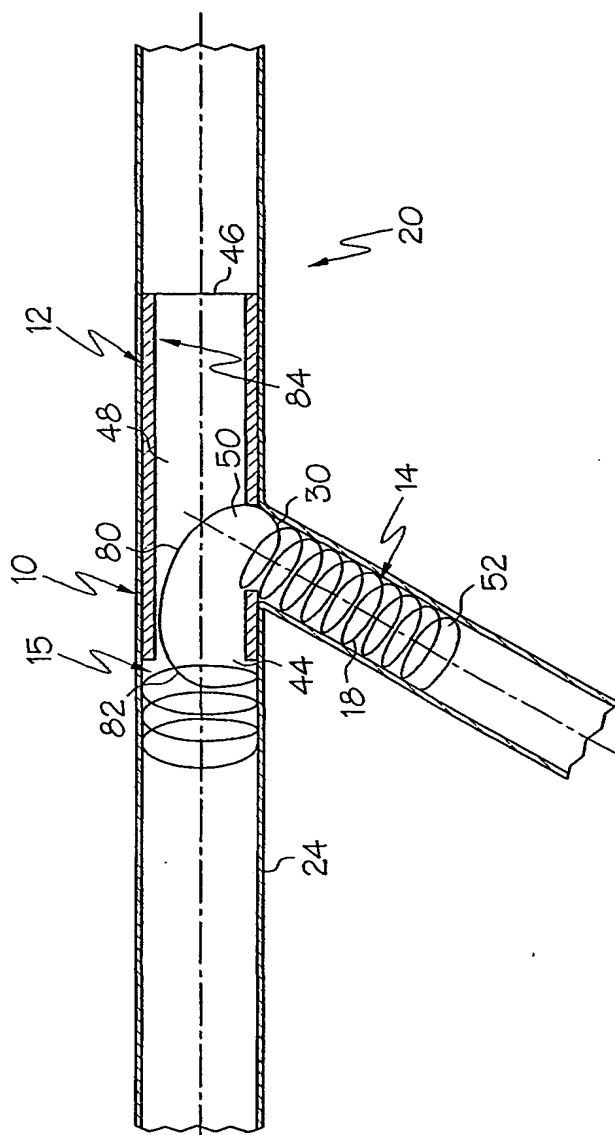


FIG. 12

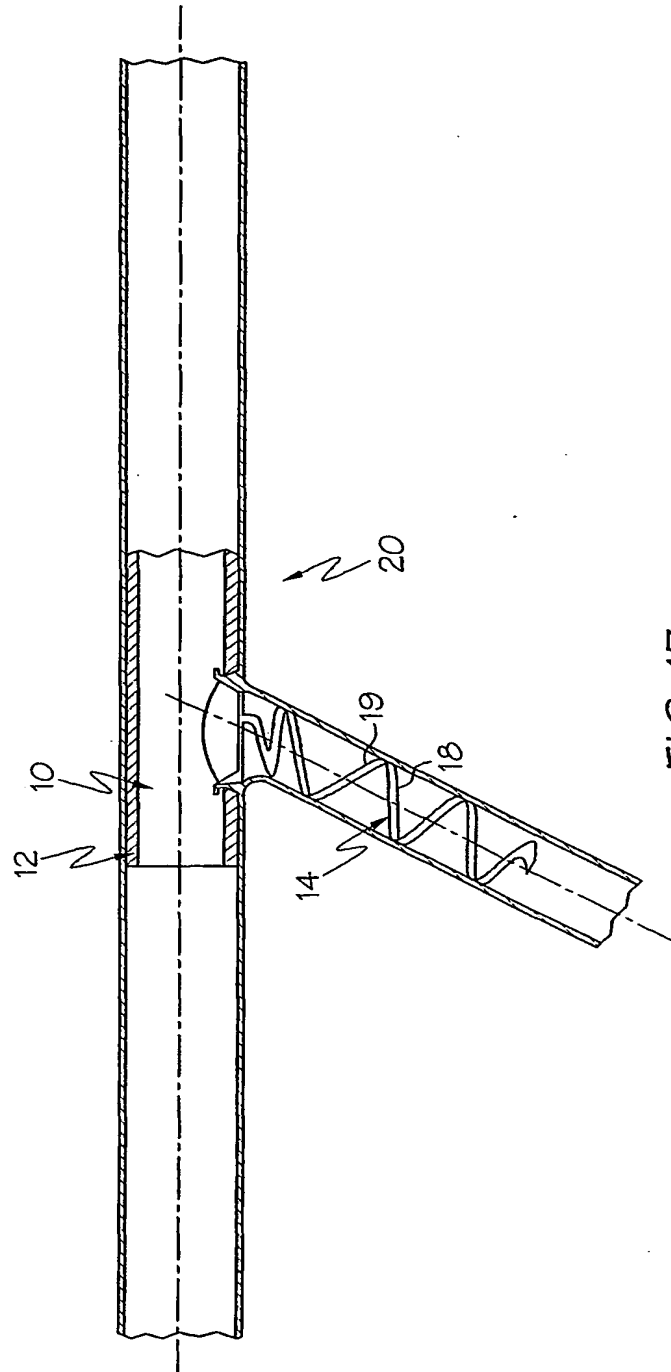
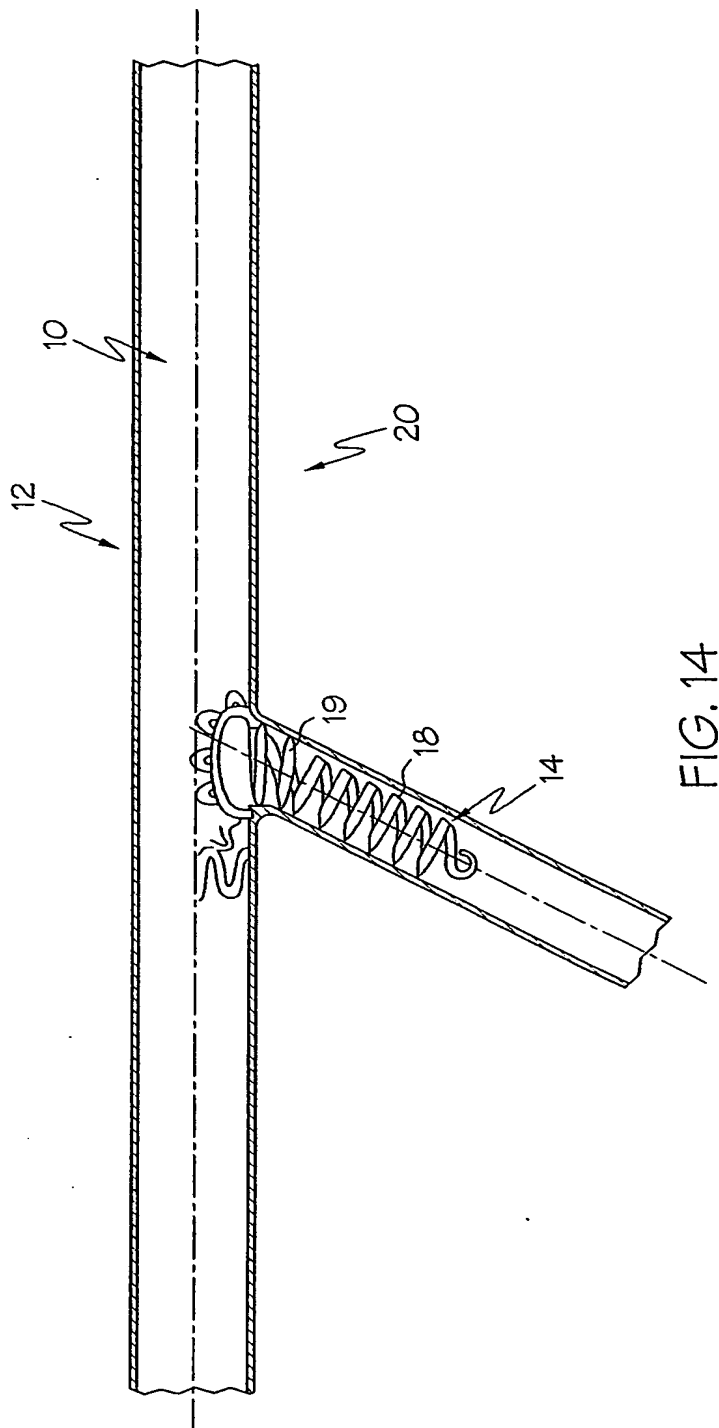


FIG. 13





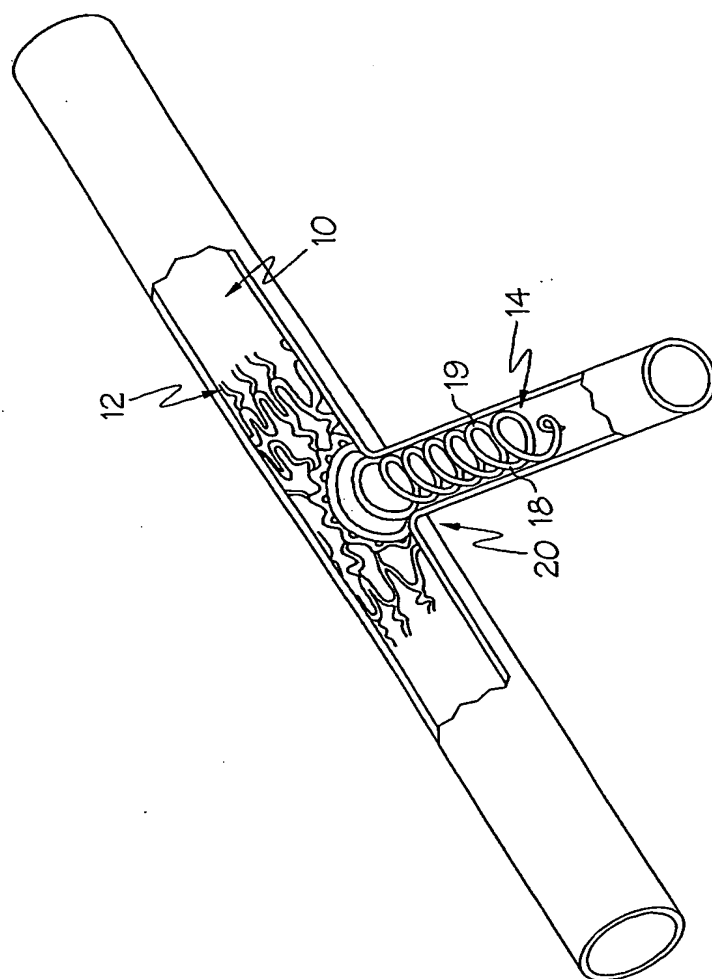


FIG. 15

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/06155

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 961 548 A (SHMULEWITZ ASCHER) 5 October 1999 (1999-10-05) column 3, line 27 - line 35; claims 1,6,8,13; figures	1-5,7,9, 11
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X	FR 2 678 508 A (CELSA LG) 8 January 1993 (1993-01-08) page 5, line 17 - line 34; claim 6; figure 4	1-4,9
A		20-27
X	WO 99 36002 A (ELAM ERIC ; VARDI GIL M (US); LIN STUART (US); ADVANCED STENT TECHN) 22 July 1999 (1999-07-22) page 9, line 9 - line 16; figures	1,10,12, 13,16, 20,24,26
	-/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

19 July 2002

Date of mailing of the international search report

26/07/2002

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Int lional Application No

PCT/US 02/06155

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X	WO 99 15103 A (VONDERWALDE FREIDBERG CARLOS) 1 April 1999 (1999-04-01)  page 4, line 17 -page 6, line 18; figures	1-3,5,7, 10, 12-14,16
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International Application No

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			JP 2001517482 T	09-10-2001